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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/019,816

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Michael Valentine Agrez

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/019,816	<b>Applicant(s)</b> AGREZ ET AL.	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 217-219,221,225,238,277 and 283-285 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 217,219,221 and 225 is/are allowed.
- 6) ☒ Claim(s) 218,238,277 and 283-285 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

Art Unit: 1643

### **DETAILED ACTION**

Claims 244, 272 and 275 have been deleted. Claims 217-219 have been amended. Claims 283-285 have been added. Claims 217-219, 221, 225, 238, 277 and 283-285 are pending and under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 218, 238, 277 and 283-285 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 238 is vague and indefinite in the recitation of “other areas of the mouth” and “other oral cavities”. Firstly, it is unclear if the buccal mucosa, tonsil, tonsillar pillar, soft palate or the hard palate are included in “other areas of the mouth”. Secondly, it is unclear what “other oral cavities” encompass as said claim enumerates all known oral cavities recognized in the art.

It is unclear how claim 218 further limits claim 217, because limitation of the polypeptide of claim 217 to only the binding domain for the ERK2 MAP kinase does not account for the linker sequence required in claim 217.

It is unclear how claim 277 further modifies claim 217 because claim 217 requires the entirety of SEQ ID NO:2, 22 and 23 in addition to a linker sequence and therefore cannot accommodate sequences which are obviously shorter than the required SE ID NO:2, 22 and 23 notwithstanding the linker sequence..

It is unclear how claim 283 further modifies claim 277, because as stated above, the base claim requires the entirety of SEQ ID NO:2, 22 and 23 in addition to a linker sequence and therefore cannot accommodate sequences which are obviously shorter than the required SE ID NO:2, 22 and 23 notwithstanding the linker sequence.

It is unclear how claim 283 further modifies claim 217. Claim 217 requires the non-essential amino acid linker sequence. Thus, claim 284 which negates this requirement, is not within the scope of claim 217.

Art Unit: 1643

It is unclear how claim 285 further modified claim 284. claim 285 requires SEQ ID NO:3 which is not part of the scope of claim 284.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 283-285 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 283 requires that the polypeptide of claim 277 be 10 amino acids or 15 amino acids in length. The originally filed disclosure states that polypeptide are preferable from about 5 to 30 amino acids, and more preferable between 5 to 25 amino acids. Thus the amendment to require 10 amino acids or 15 amino acids is not supported by the specification as filed. It is noted that the "polypeptide" of claim 217 includes SEQ ID NO:2, 22 and 23, which are all 15 amino acids in length in addition to the linker sequence, and therefore cannot be a minimal length of 15 amino acids or less.

Claims 283 and 284 encompass the treatment of cancer comprising the administration of SEQ ID NO:2, 3, 22 or 23 wherein the amino acids sequences of SEQ ID NO:2, 3, 22 or 23 are administered without a carrier peptide or auxiliary sequence to stabilize said peptide and facilitate cellular entry. The originally filed disclosure does not support the direct administration of SEQ ID NO:2, 3, 22 or 23 out of the context of a fusion protein (pages 54-55, bridging paragraph and final paragraph on page 55). . One of skill in the art would reasonable conclude that applicant was not in possession of the claimed method at the time of filing.

Claims 217, 219, 221 and 225 are allowed.

Art Unit: 1643

Claims 218, 238, 277 and 283-285 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643